REMARKS

In view of the following remarks, the Examiner is requested to allow claims 1, 2, 6-9, 11, 31-41, 43-45, the only claims pending and under examination in this application.

Claims 1, 11 and 36 have been amended. Support for these amendments may be found throughout the specification and claims as originally filed. For instance, support may be found at paragraphs 17, 40, 51 and 52. Claims 10 and 42 have been cancelled. Accordingly, no new matter has been added and entry of the above amendments is respectfully requested.

The Examiner is thanked for the personal interview held with the undersigned on May 23, 2006. During the interview, the Examiner agreed that the Finality of the Office action mailed on March 9, 2006 would be withdrawn. In addition, potential amendments were discussed.

Finality of the Office Action

As reviewed in the above summarized interview, the Amendment that was filed on March 9, 2006 in conjunction with the Request for Continued Examination contained new Claims 44 and 45. Claim 44 is directed to a method for the controlled delivery of flowable orthopedic cement composition without the use of substantial pressure, wherein any pressure applied to the cement during delivery does not exceed about 100 psi. Claim 45 is directed to the method of Claim 44, wherein any pressure applied to said cement during delivery ranges from about 1 to about 100 psi. The Examiner agreed during the above summarized interview to withdraw the finality of the March 9, 2006 office action

Claim Rejections – 35 U.S.C. § 102

Claim Rejections – 35 U.S.C. § 102

Claims 1-2, 7-9, 11, 31-33, 36-38, 40-41 and 43-45 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* (USPN 6,149,655).

According to the M.P.E.P., a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. § 2131.

As amended, an element of Claims 1, 11 and 36 is:

"positioning at said cancellous bone target bone site an end of a flowable composition introductory element that is present in a holder of a vibratory element.."

This element is simply not taught, or even suggested, in Constantz.

Furthermore, an element of Claims 1, 11 and 36 is that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Constantz does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops simultaneously with the cessation of vibration.

The Office, however, asserts that because Constantz discloses the use of vibration to enhance infiltration of the cement, Contantz necessarily teaches that when vibration is stopped infiltration is also "simultaneously stopped" because the driving force for the cement delivery would be removed.

The Applicants respectfully disagree and contend that the conclusion of the Office is unfounded and not supported by the teachings of Constantz. Nowhere does Constantz teach that penetration of the cement stops simultaneously with cessation of vibration. Additionally, Constantz does not set forth any working examples showing the use of vibration without the application of pressure let alone examples showing that the cement flow stops simultaneously with cessation of an applied force. Rather, Constantz discloses the following:

> "Instead of, or in addition to, the application of pressure to the cement, cement delivery into and perfusation of the cement throughout the cancellous region of the compromised vertebral body being treated may be enhanced by applying external energy to the at least the region of cancellous bone where the presence of the calcium phosphate cement is desired. By external energy is meant physical energy, such as motion, which may be in the form of agitation, vibration, sonic wave and the like. Any means of introducing this external energy to the region of cancellous bone to be infiltrated may be employed."

As the Office points out, the use of vibration as disclosed in Constantz is to enhance (e.g., increase) infiltration of the cement. While the addition of a given force may heighten or increase a given action, it does not necessarily follow that removal of that force would stop the action from occurring. For instance, an object in motion will continue in motion unless acted upon by an opposing force. Simply increasing an initial flow by adding an additional impulse does not mean that when the additional impulse is removed the initial flow will automatically stop. In fact, the Applicants contend that this is especially true for thixotropic fluids.

Thixotropic fluids are those that change their viscosity due to agitation, such as vibration. The change in viscosity of a thixotropic fluid is time dependent. Therefore, the longer the fluid is under a shear force the less viscous it becomes. The less viscous the fluid becomes the greater will be its rate of flow. Hence, because the change in viscosity of a thixotropic fluid is time dependent, removal of the shear force does not mean that the fluid instantaneously becomes so viscous that its flow simultaneously

ceases with the cessation of the applied force. Rather the fluid's flow will continue until its viscosity increases to a point where the initial impulse is overcome by friction. Ketchup, for instance, is a thixotropic fluid that becomes increasingly less viscous due to the application of a vibratory force such that even when the vibratory force applied to a ketchup container ceases the ketchup, once moving, will continue to flow, often in undesired quantities.

Accordingly, given the particulate formulation and charged nature of the calcium phosphate cement mixture disclosed in Constantz, the Applicants contend that one of skill in the art would have interpreted the cement mixture to be a thixotropic fluid. Accordingly, one of skill in the art would expect the calcium phosphate cement to act like a thixotropic fluid and become less viscous in response to vibration in a time dependent manner. As the cement were to become less viscous its flow would increase. Therefore, contrary to the assertion by the Office, one of skill in the art, in view of the thixotropic aspect of the calcium phosphate cement, would have expected the flow of the cement mixture to continue, even after the applied vibratory force is removed, until the fluid's viscosity increased to a point whereby the momentum transferred to the fluid by the vibratory force was overcome by the increased viscosity of the fluid.

Hence, the conclusion by the Office is unfounded in that one of skill in the art would not expect that when the driving force of the cement is stopped the flow (e.g., delivery) of the cement would also be "simultaneously stopped." Accordingly, because one of skill in the art, in view of Constantz, would not expect the flow of the cement to stop simultaneously when the driving force is stopped, Constantz does not teach that penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

In view of the above, Constantz does not teach every element of the rejected claims because Constantz does not teach:

a) "positioning at said cancellous bone target bone site an end of a flowable composition introductory element that is present in a holder of a vibratory element..." or

b) that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Therefore, the Applicants respectfully request that the rejection of Claims 1-2, 7-9, 11, 31-33, 36-38, 40-41 and 43-45 under 35 U.S.C. § 102(b) over Constantz be withdrawn.

Claim Rejections – 35 U.S.C. § 102/103

Claims 10 and 42 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* or, in the alternative, under 35 U.S.C. 103(a) as allegedly being obvious over Constantz *et al.* As Claims 10 and 42 have been cancelled, this rejection may be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claim 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Sproul (USPN 6,832,988).

Claim 6 depends from Claim 1 and additionally includes the step of aspirating marrow from the cancellous bone.

As set forth above, Claim 1 includes the following elements:

a) "positioning at said cancellous bone target bone site an end of a flowable composition introductory element that is present in a holder of a vibratory element..." and

b) that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Constantz fails to teach or suggest the claimed positioning step. Furthermore, Constantz is deficient in that it neither teaches nor suggests that the penetration of the orthopedic cement into the target bone site stops simultaneously with the cessation of vibration. As set forth above, Constantz does not suggest this element because one of skill in the art would understand Constantz to teach, or at least suggest, that the penetration of the cement into the target bone site continues after the cessation of vibration, which is the opposite of what the Applicants are claiming.

As Sproul is recited solely for its disclosure of aspiration during vertebroplasty it fails to remedy the defects of Constantz.

In view of this, the combination of Constantz and Sproul fail to teach or suggests every element of Claim 6 and the Applicants respectfully request the § 103(a) rejection of Claim 6 be withdrawn.

Claims 34, 35 and 42 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Seki (USPN 4,961,817).

Claims 34 and 35 ultimately depend from Claim 11. Claim 42 ultimately depends from Claim 36. Claims 34, 35 and 42 incorporate all the elements of Claims 11 and 36 and additionally recite the element of a vibratory element, e.g., a pneumatic vibratory element.

As set forth above, Claims 11 and 36 include the following elements:

a) "positioning at said cancellous bone target bone site an end of a flowable composition introductory element that is present in a holder of a vibratory element..." and

b) that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Constantz fails to teach or suggest the claimed positioning step. Furthermore, Constantz is deficient in that it neither teaches nor suggests that the penetration of the orthopedic cement into the target bone site stops simultaneously with the cessation of vibration. As set forth above, Constantz does not suggest this element because one of skill in the art would understand Constantz to teach, or at least suggest, that the penetration of the cement into the target bone site continues after the cessation of vibration, which is the opposite of what the Applicants are claiming.

As Seki is recited solely for its disclosure of a pneumatic vibrator for vibrating a needle-like member it fails to remedy the defects of Constantz. Accordingly, a *prima facie* case of obviousness has not been established because the recited combination fails to teach every element of the rejected claims.

Additionally, even if the cited combination were to teach every element of the rejected claims a *prima facie* case of obviousness is still not established because Seki constitutes non-analogous art to the Applicants' claimed invention.

According to the M.P.E.P. § 2141.01 in order for the Office to rely on a reference as a basis for rejection of the Applicants' invention, the reference must either be in the field of the Applicants' endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.

Seki constitutes non-analogous art to the Applicants' claimed invention because it is not in the Applicants' field of endeavor nor reasonably pertinent to the particular

problem with which the Applicants were concerned. Rather, Seki is directed to a thin-film releasing technique for releasing a thin film stuck on a substrate and for drawing off the released thin film.

The Applicants' field of endeavor is the delivery of orthopedic cements. The particular problem the Applicants are concerned with is the controlled delivery of orthopedic cement to a target bone site without the substantial application of pressure in a manner such that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Seki, however, is directed to the production of thin films on a substrate and their subsequent release once they are produced. Accordingly, because Seki is not directed to the delivery of orthopedic cements to a target bone site, it is not in the Applicants' field of endeavor.

Additionally, Seki is not concerned with the controlled delivery of orthopedic cement without the substantial application of pressure in a manner such that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration. Accordingly, Seki is not reasonably pertinent to the particular problem with which the Applicants were concerned.

The Office, however, asserts that Seki is pertinent to the particular problem with which the Applicants were concerned because Seki discloses a pneumatic vibration generating mechanism. The Applicants respectfully disagree and contend that Seki is not concerned with the delivery of a fluid to a bone site via the use of a vibratory force and does not recognize the tremendous physiological problems that an uncontrolled flow of a delivered fluid can have on the body. Rather, Seki is simply concerned with releasing a thin film from a production apparatus. Hence, the Applicants contend that one of skill in the art would not look to Seki to solve the problems caused by uncontrolled fluid delivery to target bone sites.

Therefore, Seki represents non-analogous art because it is neither in the Applicant's field of endeavor nor is it reasonably pertinent to the problem with which the Applicant was concerned. Accordingly, one of reasonable skill in the art would not look to Seki for guidance as to the delivery of orthopedic cement to a target bone site.

In view of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the cited combination does not teach every element of the rejected claims and even if all the elements are taught Seki constitutes non-analogous art. Accordingly, the Applicants respectfully request this rejection be withdrawn.

Claim 39 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.*

The Office asserts that Constantz discloses all the elements of the claimed invention except for the limitation that the amount of cement to be delivered is from about 4 to 10 cubic centimeters. Nevertheless, the Office asserts that it would have been obvious to one of skill in the art to deliver about 4 to 10 cubic centimeters of cement. To support this conclusion the Office relies upon *In re Aller* for the proposition that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill.

The Applicants respectfully disagree for the following reasons.

First of all, Claim 39 ultimately depends from independent Claim 36.

As set forth above, Claim 36 includes the following elements:

a) "positioning at said cancellous bone target bone site an end of a flowable composition introductory element that is present in a holder of a vibratory element..." and

b) that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration.

Constantz fails to teach or suggest the claimed positioning step. Furthermore, Constantz is deficient in that it neither teaches nor suggests that the penetration of the orthopedic cement into the target bone site stops simultaneously with the cessation of vibration. As set forth above, Constantz does not suggest this element because one of skill in the art would understand Constantz to teach, or at least suggest, that the penetration of the cement into the target bone site continues after the cessation of vibration. In view of this, Constantz fails to teach or suggest every element of Claim 39.

Additionally, the Applicants contend that *In re Aller* does not apply to the present case. In *In re Aller* the Applicant had claimed a process that was identical to the prior art in everyway except with respect to the recitation of the specific temperature and acid concentration to be used. See *In re Aller*, 42 C.C.P.A. 824, 827 (1955). The present case is different from *In re Aller* because Claim 39 recites an element that is completely missing from Constantz, namely, the element that when the vibration stops the penetration of the cement stops simultaneously with the cessation of vibration. Accordingly, the present case is distinguishable from *In re Aller* in that the claimed process is not identical to that of the prior art.

Furthermore, in *In re Aller* the only change in the process between what was claimed and what was disclosed in the prior art was the exact temperature and reagent concentration. However, the prior art still set forth an initial temperature and reagent concentration. Here, the cited prior art is completely silent as to how much cement is to be introduced into vertebral bodies. Accordingly, because the prior art is completely silent as to the amount of cement to be delivered it is erroneous for the Office to

assume pursuant to *In re Aller* that the Applicants' claimed range is simply a matter of optimizing the prior art range as no prior art range was provided. Hence, the Applicants contend that *In re Aller* cannot be relied upon to render Claim 39 obvious.

Finally, the Applicants note that the claimed amount of cement that can be introduced into each side is unexpectedly greater than the amount that can be introduced without vibration. Specifically, without vibration the amount that can be introduced into each side is, one average, 1. 5 to 2 cc, whereas the claimed range is 4 to 10 cc. It was not known, prior to the Applicants' work as reported herein, that one could inject this amount into each side of a vertebral body and it was not expected that vibration would allow such large amounts to be injected.

Therefore, in view of the above, the Applicants respectfully request the §103 (a) rejection of Claim 39 be withdrawn.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SKEL-012.

Respectfully submitted,
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Date: June 9, 2006

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